UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: TECFIDERA ANTITRUST LITIGATION	)	No. 24-cv-7387
	)	Judge April M. Perry

OPINION AND ORDER

In 2013, Biogen Inc. began selling Tecfidera, a prescription drug containing the compound dimethyl fumarate which was approved for the treatment of multiple sclerosis ("MS"). For years, Biogen was the sole seller of a dimethyl fumarate-based MS drug due to a patent preventing other companies from selling generic versions. In 2020, however, Tecfidera lost patent protection, opening the doors for Biogen's competitors to begin selling generic dimethyl fumarate at substantially lower prices than Tecfidera.

Plaintiffs are health benefit plans or the sponsors of health benefit plans. As such, they pay a portion of the cost of prescription drugs purchased by their members. Plaintiffs engaged the services of entities called pharmacy benefit managers ("PBMs") to help Plaintiffs negotiate prices with drug manufacturers and reduce costs by steering their members towards the purchase of lower-priced, generic versions of more expensive brand products. This case concerns Plaintiffs' allegations that to maintain its dominance in the market for fumarate-based MS drugs, Biogen bribed PBMs to direct Plaintiffs' members away from generic dimethyl fumarate and towards Biogen's more expensive brand products, causing Plaintiffs to buy more of Biogen's drugs at higher prices than they would have otherwise.

In a previous decision, the Court granted a motion by Biogen to dismiss Plaintiffs' antitrust claims. *See* Doc. 98 (opinion and order). Plaintiffs now return with bolstered allegations and a new claim brought under the Racketeer Influenced and Corrupt Organizations Act ("RICO"). Doc. 99. This opinion resolves Biogen's new motion seeking dismissal of Plaintiffs' second amended complaint. Doc. 111. For the following reasons, the Court denies the motion to dismiss in its entirety.

BACKGROUND

Plaintiffs' second amended complaint contains the same core story as was told in the first amended complaint.[1] Given the complexity of the industry from which these claims arise, the Court will restate the relevant background facts from its previous decision, supplementing as appropriate with details drawn from Plaintiffs' second amended complaint.

I. Pharmaceutical Sales in the United States

In the United States, the sale of pharmaceuticals is regulated by the Federal Food, Drug, and Cosmetic Act ("FDCA") and its 1984 amendments (commonly referred to as the "Hatch-Waxman Amendments" or "Hatch-Waxman Act"). Doc. 99 ¶ 128. Under the FDCA, a company seeking to market a new drug must seek approval from the U.S. Food and Drug Administration ("FDA") by submitting a New Drug Application ("NDA"). *Id.* This application process is intense and requires an applying company to submit data from clinical studies showing the proposed drug is both safe and effective. 21 U.S.C. §§ 355(a), (b). Applying companies must also submit the "patent number and expiration date of each patent for which a claim of patent infringement

[1] In the middle of briefing the motion to dismiss, Plaintiffs filed a third amended complaint, Doc. 119, removing one of the plaintiffs but making no substantive changes to the allegations or claims. This opinion therefore references the second amended complaint but applies with equal force to the third amended complaint.

could reasonably be asserted." *Id.* §§ 335(b)(1)(viii). New drugs approved through the NDA process are generally referred to as brand-name or brand drugs.

Clinical testing and other costs associated with the NDA process can be substantial. Doc. 99 ¶ 131; *see also F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 142 (2013). However, brand drugs typically enter the market under the protection of patents that prevent rival companies from selling competing products. *Id*. ¶ 129. This patent-enabled market exclusivity insulates brand drugs from price competition and enables manufacturers to recoup development and approval costs by selling brand drugs well above their per-unit manufacturing cost. *See id*. ¶ 4.

Once a brand drug loses its patent protection, competing manufacturers can begin selling therapeutically identical versions of the brand drug, *i.e.*, generics. Like brand manufacturers, generic manufacturers must also submit their drugs for approval by the FDA. Before the Hatch-Waxman Act, this meant undergoing the same expensive and time-consuming NDA process as brand manufacturers. Unlike brand manufacturers, however, generic manufacturers cannot rely on a period of patent-enabled market exclusivity to recoup costs associated with the clinical testing and application process. Recognizing this, Congress introduced via the Hatch-Waxman Act a new regulatory pathway to promote the development and launch of generics. This pathway, named the Abbreviated New Drug Application ("ANDA"), permits a generic manufacturer to reduce costs by relying on the clinical studies submitted in connection with an already-approved brand drug's NDA. *Id.* ¶ 130–31. The effect of generic entry on the market for a given drug can be significant: generics typically sell for a fraction of the cost of their brand counterparts, which often means generics capture more than ninety percent of the market within the first six months of availability. *Id*. ¶ 139.

But FDA approval is only the first step in getting lower-cost generics to patients. Some medications may only be sold to patients with a physician's approval, *i.e.*, a prescription. *See id.* ¶ 124. With a prescription, a patient can purchase the prescribed medicine from a pharmacy. If the patient has health insurance, she will typically pay only a portion of the drug's total price while her plan covers the remainder. This cost-sharing perk of health plan coverage is called a pharmacy benefit or prescription drug benefit.

Most consumer products are selected and paid for by the same individual, meaning price plays a significant role in both purchasing decisions and spurring competition between rival sellers. *Id*. ¶ 123. But for a few reasons, this price-quality calculus does not play out neatly in prescription drug markets. For one, a patient's choice of medicine is made in part by their doctor, who prescribes a drug but pays none of its cost and thus has "no incentive to take the price into account." *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 646 (2d Cir. 2015); *see also* Doc. 99 ¶¶ 125–26. Moreover, due to cost-sharing between patients and plans, patients are not always incentivized to select a generic: what matters to the patient is what they pay out-of-pocket.

To motivate their members to select lower-cost generics, plans call on the service of PBMs. PBMs provide plans with a number of services related to the administration of pharmacy benefits, *id*. ¶ 164, one of which is the creation and management of formularies. *Id*. ¶ 142. Formularies are documents that identify which drugs a health plan will cover and the cost-sharing of covered drugs. *Id*. When creating formularies, PBMs sort drugs into "tiers." *Id.* ¶ 147. A drug's tier determines what share of its cost must be paid out-of-pocket by an insured patient when a prescription is filled. *Id.* Drugs in lower tiers will generally have a lower cost for patients compared to drugs in higher tiers. *Id.* ¶¶ 147–48. Thus, because generics cost less overall, plans

benefit when PBMs place generics in lower tiers than brand counterparts, as this incentivizes their members to demand or accept the generic version. *Id.* ¶ 149. PBMs can also motivate insureds to select or avoid certain drugs in other ways. For example, PBMs may subject certain drugs to a prior authorization requirement (*i.e.*, conditioning coverage of a specific drug on the PBMs' review and approval) or step edit policy (*i.e.*, requiring a patient to try an alternative treatment before becoming eligible for coverage). *Id*. ¶ 151.

According to Plaintiffs, PBMs possess superior knowledge and expertise over plans when it comes to the negotiation of drug prices and formulary placement. *Id*. ¶ 156. Plans lack the resources and expertise to develop formularies on their own, and so rely on PBMs to make formularies for them and to act as intermediaries with drug manufacturers with respect to drug price negotiations. *Id*. Indeed, PBMs market themselves as trustworthy experts in formulary design, through promotional statements touting their expertise and promising to reduce costs for their health plan clients. *See id*. ¶ 157–62. In part due to this gap in expertise, negotiations between plans and PBMs regarding formulary management generally cover only broad and aggregate issues, rather than the placement or pricing of particular drugs on a formulary that might contain thousands of medicines. *Id*. ¶¶ 165, 167. Moreover, the contracts between plans and PBMs give PBMs the power to unilaterally add, subtract, or change the tiering of drugs on their formularies. *Id*. ¶ 168. PBMs do not share details of formulary changes with their plan clients. *Id*. ¶¶ 169–70.

Because of their control over formularies, Plaintiffs allege that brand manufacturers sometimes make payments to PBMs—in the form of rebates and fees—in exchange for more favorable tiering of their products. *Id.* ¶ 185. While these payments are highly lucrative to PBMs,

they can also cause plans and patients to buy more expensive brand products even when less expensive generics are available. *Id.*

II. Tecfidera and its Generics

MS is an autoimmune disease which causes a person's immune system to attack their nerves, which can lead to degenerative symptoms like blindness, loss of mobility, pain, and paralysis. *Id.* ¶¶ 213–14. In 2013, the FDA approved the NDA that allowed Biogen to begin selling Tecfidera for MS. *Id.* ¶ 217. Tecfidera contains dimethyl fumarate, which the body metabolizes into monomethyl fumarate, the molecule that provides Tecfidera its therapeutic effects. *Id*. ¶ 16. Financially, the drug was a major success: between 2015 and 2019, sales of Tecfidera comprised almost half of Biogen's total U.S. product sales, peaking at $3.3 billion sold in 2019. *Id*. ¶ 218.

When launched, Biogen held a patent that prevented rival drug companies from selling generic versions of Tecfidera. *Id*. ¶ 217. Beginning in 2017, however, that patent came under legal challenge and was ultimately invalidated in mid-2020. *Id*. ¶¶ 225–26. In August 2020, the FDA approved the first generic version of Tecfidera, with several other generics entering the market in the following months. *Id*. ¶ 227. Within seven months of entering the market, these generics were selling for as low as $14 per pill compared to Tecfidera's per-pill price of $132. *Id.* ¶ 235.

III. Alleged Anticompetitive Conduct

Plaintiffs allege Biogen engaged in a number of tactics to avoid competition from generics and thus preserve its dominant position in the market for fumarate-based MS drugs. As described below, these include allegations that Biogen (1) launched a new brand drug, Vumerity, to avoid generic substitution; (2) paid PBMs to make generic dimethyl fumarate more expensive

and harder to access; and (3) offered coupons to insureds to cover the out-of-pocket costs for Tecfidera, which made Tecfidera a more enticing option to patients even though the aggregate cost of the brand drug was still higher than that of generic dimethyl fumarate.

a. Vumerity

During the pendency of litigation over the Tecfidera patent, Biogen submitted an NDA for diroximel fumarate, the patent for which would not expire until October 2033. *Id.* ¶¶ 308–9. Diroximel fumarate converts in the body into monomethyl fumarate, the same active ingredient that gives Tecfidera and generic dimethyl fumarate their therapeutic effects. *Id.* ¶ 311. This meant Biogen was able to rely on the clinical data demonstrating Tecfidera's safety and effectiveness to support its NDA for diroximel fumarate. *Id.* ¶ 310.

In October 2019, the FDA approved the NDA for diroximel fumarate, which Biogen launched under the brand name Vumerity. *Id.* ¶ 322. To convince doctors and patients to switch from Tecfidera to Vumerity, Biogen promoted Vumerity to doctors, patient groups, state Medicaid committees, and PBMs as having fewer gastrointestinal ("GI") side effects relative to Tecfidera. *Id.* ¶¶ 331, 335–36, 361–63, 365, 370–71. According to Plaintiffs, Biogen pressed these claims despite the FDA's conclusion that none of the data Biogen submitted with its diroximel fumarate NDA showed any such GI improvements relative to Tecfidera. *Id.* ¶¶ 352–53. And indeed, Biogen itself later admitted its doubts about the reliability of clinical data underlying its GI superiority claims. *Id.* ¶ 359.

Nonetheless, Biogen was at least partially successful in achieving its goal of changing prescription patterns, as evidenced by Vumerity's capture of a roughly twenty-five percent share of the fumarate-based MS treatments market, rather than the five percent that the complaint alleges Vumerity would have achieved under competitive conditions. *Id.* ¶ 307.

b. Payments to PBMs

In tandem with Vumerity's launch, Plaintiffs allege that Biogen paid a number of co-conspiring PBMs[2] to use their control over plan formularies to make generic dimethyl fumarate more expensive and harder to access. From 2021 onward, these payments caused PBMs to disadvantage generic dimethyl fumarate relative to Biogen's brand products in three specific ways.

First, PBMs agreed to place generic dimethyl fumarate in the equivalent (or worse) formulary tier as Tecfidera. *Id*. ¶ 236. In 2021, this manipulation affected formularies covering roughly forty percent of all insureds. *Id*. ¶ 248.

Second, PBMs agreed to designate generic dimethyl fumarate a specialty drug, limiting the number of pharmacies able to dispense it. *Id*. ¶ 258. Medicines designated as specialty drugs may be dispensed only from a designated subset of 'specialty pharmacies' that charge higher prices than non-specialty pharmacies. *See id*. ¶¶ 10–11. Thus, specialty designation of generic dimethyl fumarate caused affected insureds to incur higher out-of-pocket costs than they would have otherwise. *Id*. ¶ 262. According to Plaintiffs, Biogen offered enhanced rebates and fees for PBMs to designate generic dimethyl fumarate a specialty drug on formularies where brand Tecfidera was also so designated. *Id*. ¶ 259. These manipulations resulted in around sixty percent of insureds paying higher prices than they would have absent the designation. *Id.* ¶ 271.

Third, PBMs agreed to impose prior authorization and step edit requirements on generic dimethyl fumarate. Specifically, PBMs required some insureds to satisfy the requirement of first

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[2] Specifically, Plaintiffs name Caremark Rx, LLC, OptumRx, Inc., Express Scripts, Inc., Humana Pharmacy Solutions, Inc., and MedImpact Healthcare Systems, Inc. as the PBMs that joined with Biogen to effectuate the alleged scheme. Doc. 99 ¶ 5. Collectively, these five PBMs control pharmacy benefits for more than 90% of Americans. *Id.*

trying another MS drug—such as Tecfidera or Vumerity—before their plan would cover generic dimethyl fumarate *Id*. ¶ 276. PBMs also made it so some insureds could not access generic dimethyl fumarate at all unless their doctors made formal requests to the PBM for coverage approval. *Id*. ¶ 277. As alleged, these were no more than bureaucratic roadblocks designed to make generic dimethyl fumarate harder for insureds to access.

c. Coupons

In addition to new product launch and payments to PBMs, Biogen also offered coupons to insureds covering their out-of-pocket copay or coinsurance obligations for Tecfidera. *Id*. ¶ 288. According to Plaintiffs, these coupons undermined the price advantage of generics over brand Tecfidera and led insureds to buy brand Tecfidera despite the fact that the total price paid by insureds and their plans exceeded what would be paid for the generic.

LEGAL STANDARD

A motion to dismiss under Rule 12(b)(6) challenges the sufficiency of the complaint, not its merits. FED. R. CIV. P. 12(b)(6); *Gibson v. City of Chicago*, 910 F.2d 1510, 1520 (7th Cir. 1990). In considering a Rule 12(b)(6) motion, the Court accepts as true all well-pleaded facts in a plaintiff's complaint and draws all reasonable inferences from those facts in a plaintiff's favor. *Kubiak v. City of Chicago*, 810 F.3d 476, 480-81 (7th Cir. 2016). "While a complaint ... does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations omitted).

ANALYSIS

Biogen's motion seeks dismissal of all ten of Plaintiffs' claims, which include eight claims under the Sherman Act and its state law analogs (Counts I–IV, VII–X), one claim under the Robinson-Patman Act (Count V), and one RICO claim (Count VI). Biogen's first line of attack is that Plaintiffs' claims are barred, in whole or in part, by doctrines limiting recovery in antitrust and RICO cases to only the most directly injured entities, which Biogen contends Plaintiffs are not. The Court will start there before proceeding to the plausibility of Plaintiffs' various claims.

I. Directness

Biogen argues that two limiting doctrines bar Plaintiffs' claims. First, they argue that the direct purchaser rule laid out in *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977) blocks Plaintiffs' claims for money damages under the Sherman Act (Counts I–IV), Robinson-Patman Act (Count V), and RICO (Count VI). Biogen also argues that Plaintiffs may not pursue injunctive relief under the Sherman Act or Robinson-Patman Act because they are not the most directly injured victims of Biogen's alleged misconduct.

Illinois Brick instructs that a "downstream plaintiff cannot sue an alleged monopolist or cartel member on a theory that a middleman passed an anticompetitive overcharge on to her." *Marion Healthcare, LLC v. Becton Dickinson & Co.*, 952 F.3d 832, 838 (7th Cir. 2020). The purpose of the rule is to avoid "the risk of duplicative recovery engendered by allowing every person along a chain of distribution to claim damages arising from a single transaction." *Blue Shield of Virginia v. McCready*, 457 U.S. 465, 474–75 (1982). By the same token, an antitrust claim for damages does not raise *Illinois Brick* concerns if allowing it to proceed does not risk "the slightest possibility of duplicative exaction." *Id.* at 475. A similar

direct purchaser rule applies to RICO claims. *Carter v. Berger*, 777 F.2d 1173, 1177 (7th Cir. 1985).

Plaintiffs have stipulated that they "are no longer seeking damages in connection with their causes of action under Sections 1 and 2 of the Sherman Act." Doc. 128 ¶ 3. As the *Illinois Brick* rule is generally understood only to bar actions for monetary relief, *U.S. Gypsum Co. v. Indiana Gas Co., Inc*., 350 F.3d 623 (7th Cir. 2003) ("the direct purchaser doctrine does not foreclose equitable relief"),[3] it thus has no bearing on Plaintiffs' request for equitable relief under the Sherman Act, nor does it bar Plaintiffs' state law claims.[4]

Plaintiffs' claims for damages under the Robinson-Patman Act and RICO require more analysis. The thrust of both claims is that Biogen bribed PBMs to improperly influence how the PBMs designed Plaintiffs' formularies. As a result, Plaintiffs "purchas[ed] significantly more high-cost Tecfidera and Vumerity than low-cost generic Tecfidera than [they] would have otherwise." Doc. 99 ¶ 584. Plaintiffs also say the scheme allowed Biogen to "successfully charge[] higher prices for Tecfidera and Vumerity than it otherwise could have in a competitive market." *Id*.

Plaintiffs do not dispute that these claims are governed by the direct purchaser rule as a general matter: rather, they assert that the damages they seek fall outside *Illinois Brick* (and its RICO analog) because they seek redress for the "corruption of the relationship" between Plaintiffs and their hired PBMs. *See* Doc. 129 at 29–30. To this end, Plaintiffs note that they

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[3] The Supreme Court has not spoken directly on this issue, *see Apple Inc. v. Pepper*, 587 U.S. 273, n.1 (2019) ("*Illinois Brick* did not address injunctive relief, and we likewise do not address injunctive relief in this case."), and therefore this Court is bound by the Seventh Circuit's controlling precedent.

[4] Biogen argues that these claims instead fail for lack of standing. Given the allegations in the second amended complaint, the Court does not consider the alleged injuries to be too remote to confer standing.

could seek as damages only the amount that Biogen paid in bribes to the PBMs. *See Grace v. E.J. Kozin Co.*, 538 F.2d 170, 172 (7th Cir. 1976). This is persuasive, because it takes the case outside of *Illinois Brick's* downstream purchaser paradigm altogether. Under a pure bribery theory, Plaintiffs were injured not because they had to pay inflated prices for a product, but because they were forced by the scheme to buy only that product as opposed to a different and cheaper one. To the extent this is the injury alleged, it is not obvious that any third parties—pharmacies, wholesalers, or any other intermediaries sitting between Plaintiffs and Biogen in the drug supply chain—were more directly injured, if at all.

Plaintiffs also allege, of course, that Biogen took full advantage of its scheme and inflated prices (or refused to lower them). As the Court has already noted in its earlier opinion, this theory of recovery would seem to run afoul of the direct purchaser doctrine, as Plaintiffs do not allege buying Tecfidera and Vumerity from Biogen directly. But antitrust law allows for schemes with distinct injuries to different victims, and "differently situated plaintiffs might be able to raise [different] claims" based on a single course of conduct. *Loeb Indus., Inc. v. Sumitomo Corp.*, 306 F.3d 469, 481 (7th Cir. 2002). Complaints are required to plead plausible claims, not specific facts or legal theories. And dismissal of a complaint is not appropriate so long as any plausible claim may exist. *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984) ("A court may dismiss a complaint only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations."). So even though one theory of recovery might pose direct purchaser problems, the Court declines to dismiss Plaintiffs' Robison-Patman Act and RICO claims on direct purchaser grounds. At least with respect to Plaintiffs' aberrant purchasing patterns, which arose due to Biogen's alleged bribes to the PBMs, nothing in

Plaintiffs' complaint suggests to the Court that there are entities more directly injured than Plaintiffs.

Biogen's contention that lack of directness bars Plaintiffs' antitrust claims for injunctive relief largely tracks its *Illinois Brick* arguments. For the reasons already explored, the Court is not convinced that there are victims more immediately injured or well-suited to challenge Biogen's scheme than Plaintiffs themselves, at least with respect to Biogen's payments to PBMs. Accordingly, the Court finds Plaintiffs' injunctive relief claims under the Sherman Act and Robinson-Patman Act are not barred for lack of directness.

II. Sherman Act Claims

Having resolved Biogen's threshold directness arguments, the Court turns to whether Plaintiffs have plausibly alleged claims under the Sherman Act and their state law analogs. "The purpose of the Sherman Act is to protect consumers from injury that results from diminished competition." *Agnew v. Nat'l Collegiate Athletic Ass'n*, 683 F.3d 328, 334–35 (7th Cir. 2012). Section 1 outlaws any "contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations." 15 U.S.C. § 1. Section 2 imposes liability on "[e]very person who shall monopolize … any part of the trade or commerce among the several States," 15 U.S.C. § 2, and reaches conduct of both single actors and conspiracies. *Great Escape Inc. v. Union City Body Co., Inc.*, 791 F.2d 532, 540–41 (7th Cir. 1986) (elements of a conspiracy to monopolize are "the existence of a combination or conspiracy, … overt acts in furtherance of the conspiracy, … an effect upon a substantial amount of interstate commerce and … the existence of specific intent to monopolize.").

Plaintiffs assert that Biogen violated both Sections of the Sherman Act, as well as both the unilateral monopolization and conspiracy provisions of Section 2. The allegations giving rise

to the various Counts in Plaintiffs' complaint, however, largely overlap. Biogen has grouped its dismissal arguments into those pertaining to (1) Biogen's alleged payments to co-conspirator PBMs in exchange for the disadvantaging of generic dimethyl fumarate; and (2) Biogen's efforts to migrate Tecfidera patients to Vumerity. Plaintiffs do not follow this framing, emphasizing instead that they bring their payments theory under Section 1, their Vumerity-related claim under Section 2, and an overall monopolization scheme (Count IV) distinguishable from their monopolization claim focusing on the Vumerity market switch (Count III).

While not the only way to proceed, the Court thinks the most efficient way to analyze Plaintiffs' Sherman Act claims is to focus on the different types of challenged conduct rather than parsing out specific facts to specific legal theories. As explained in the previous opinion, activities that violate the antitrust laws are often "susceptible to more than one court-defined category of anticompetitive conduct." *Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 453 (7th Cir. 2020); *see also Siva v. Am. Bd. of Radiology*, 38 F.4th 569, 572 (7th Cir. 2022) (warning that in antitrust cases, "easy labels do not always supply ready answers"). For example, conspiracy to monopolize claims brought under Section 2 can often be pled alternatively as restraint of trade claims under Section 1. *See* Richard A. Posner, Antitrust Law: An Economic Perspective 216 (1976) ("As for conspiracy to monopolize, any such conspiracy is also a conspiracy in restraint of trade ...."); *see also In re Surescripts Antitrust Litig.*, 608 F.Supp.3d 629, 651 (N.D. Ill. 2022) (courts "routinely apply the same analysis" to Section 1 and Section 2 claims when predicated on allegations that are "entirely coterminous"). As such, regarding analytical framework, the Court will say only that the ultimate question in any antitrust case is to determine whether the challenged conduct "harm[s] the competitive process," *Viamedia*, 951 F.3d at 453. That is what the Court will focus on as it analyzes each category of challenged conduct.

a. Payments to PBMs

Plaintiffs allege that Biogen paid PBMs to make generic dimethyl fumarate more expensive and harder to access for Plaintiffs' members. Specifically, Plaintiffs allege that in exchange for Biogen's payments, PBMs sometimes placed generic dimethyl fumarate in the same formulary tier as brand Tecfidera, designated the generic as a specialty drug, or subjected the generic to prior authorization and step edit requirements. Plaintiffs allege that these manipulations prevented generic dimethyl fumarate from meaningfully competing with Biogen's brand products, in large part because these changes derailed the operation of state substitution laws.

Biogen argues that the new complaint fails to address two problems identified in this Court's prior opinion dismissing Plaintiffs' payments theory. The first was insufficient explanation about how substitution laws actually worked, which prevented the Court from drawing the inference that Biogen's payments stopped substitution from happening. The second regarded Plaintiffs' allegations that plans were able to choose what formularies to use, which—combined with allegations that a sizable percent of insureds were not subject to formularies affected by the anticompetitive manipulations—compelled the Court to ask why health plans could not simply select a different formulary without any problem features, and thus avoid the generic-excluding effects of Biogen's scheme.

The Court concludes that Plaintiffs' new allegations resolve both of these issues. Regarding state substitution laws, Plaintiffs explain that in states where the majority of insureds reside, substitution only occurs if the patient would pay less for the generic than its brand counterpart. Doc. 99 ¶¶ 253–57. Thus, according to the allegations in the complaint, in such states any insured on a formulary that puts generic dimethyl fumarate in the same tier as

Tecfidera loses the benefit of state substitution laws.[5] With this additional context, the Court is satisfied that equivalent or worse tiering of generic dimethyl fumarate on certain formularies plausibly disrupted the operation of state substitution laws and impeded generics from competing on the merits.[6]

Plaintiffs have also fleshed out the business relationship between plans and their PBMs. They allege that plans cannot practically detect or police PBM misconduct with respect to tiering manipulation, for reasons including plans' lack of pharmaceutical expertise, the fact that plans negotiate formulary design with PBMs at only a high, aggregate level in part because formularies contain thousands of different drugs, and because PBMs retain the ability to make unilateral changes to plan formularies after being engaged. The result of all this, Plaintiffs allege, is that health plans cannot avoid the generic-excluding impacts of formulary manipulation.

While this characterization of plan-PBM dynamics is stark and no doubt susceptible to factual dispute, the Court does not find it implausible based upon the allegations in the second amended complaint. Thus, the Court finds Plaintiffs have plausibly alleged that Biogen's payments to PBMs foreclosed generic competition, in violation of both Sections 1 and Section 2 of the Sherman Act, plus their state law analogs.

b. Market switch

Plaintiffs separately challenge Biogen's efforts to migrate Tecfidera patients to Vumerity. This is the second time the Court has considered this theory of antitrust harm, and so the Court

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[5] In some states, substitution is prohibited unless the generic costs less. In other states, mandatory substitution occurs only if the generic costs less. *See* Doc. 99 ¶¶ 253–57.

[6] Biogen disputes Plaintiffs' characterization of how at least some of these laws operate, *see* Doc. 112 at 32, but for now, the Court agrees with Plaintiffs that their complaint tells a plausible story of how these laws work, which is all that is required for the purposes of a motion to dismiss.

will highlight just a few points. As previously explained, "[p]roduct innovation generally benefits consumers," and so what distinguishes a product launch that violates the antitrust laws from one that expands consumer choice is whether the defendant engages in coercive conduct. *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 652 (2d Cir. 2015). Conduct is coercive if it prevents doctors and patients from "evaluat[ing] the product and their generics on the merits in furtherance of competitive objectives." *Id.* at 654. This determination "necessarily turn[s] on the facts and circumstances" of a case, especially in a case involving pharmaceutical markets, which are characterized by "unique separation between consumers and drug manufacturers." *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 440–41 (3d Cir. 2016). Following these principles, at least one court has allowed a market switch claim premised on misrepresentations about the safety of old versus new drug products to proceed past summary judgment. *In re Suboxone Antitrust Litig.*, 622 F.Supp.3d 22, 69 (E.D. Pa. 2022) (product hop claims premised in part on company's attempts to "deprive consumers of the ability to actively evaluate safety claims and make the choice" between two drug products).

In its prior decision, the Court found the coercion element was missing from Plaintiffs' allegations. Having considered Plaintiffs' amended complaint, the Court finds Plaintiffs have corrected that deficiency.

As alleged, Biogen made statements to both doctors and patients falsely suggesting Vumerity's improved GI safety over Tecfidera, which gave doctors a reason to direct their patients to switch from Tecfidera to Vumerity. At the same time, Biogen paid PBMs to manipulate Plaintiffs' formularies such that their insureds would pay the same or higher copay for generics as they would for Biogen's brand products. Finally, Biogen offered coupons to cover insureds' copays when paying for Biogen's brand products, making generic dimethyl fumarate

even less attractive to patients, despite the overall lower price of generics. Thus, Biogen's payments to PBMs and coupon program undermined generic dimethyl fumarate's price advantage over Biogen's brand products, eliminating any economic reason for Tecfidera patients to resist a doctor-recommended switch to Vumerity.

The plausibility of Plaintiffs' coercion story is further bolstered by the timing of Biogen's payments. Plaintiffs allege Biogen paid the highest fees and rebates to PBMs in 2021, the first full year that generic dimethyl fumarate was available on the market. Doc. 99 ¶ 199. That could be significant because if doctors only started proposing a switch from Tecfidera to Vumerity after their patients had begun enjoying the lower copays of generic dimethyl fumarate, those patients might have pushed back on their doctor's recommendation. Patient resistance might also have clued doctors in on the substantial price difference between Vumerity and generic dimethyl fumarate, and perhaps led them to more closely scrutinize Biogen's safety claims.

Biogen's arguments to the contrary largely dispute the facts underlying Plaintiffs' claims. For example, Biogen contends that clinical studies did in fact show Vumerity's improved safety over Tecfidera. The Court agrees that if Vumerity was genuinely superior to Tecfidera, that would undercut Plaintiffs' coercion claims. At this stage of litigation, however, the Court must view all evidence and draw all inferences in Plaintiffs' favor. *Kubiak v. City of Chicago*, 810 F.3d 476, 480-81 (7th Cir. 2016). Similarly, Biogen argues that its marketing statements could not have been that persuasive to doctors because Tecfidera's GI side effects were manageable and mostly affected new patients, and therefore were unlikely to cause current Tecfidera patients to switch their prescriptions. *See* Doc. 112 at 27. Maybe, but again this would require the Court to weigh competing evidence and draw inferences against Plaintiffs, which is inappropriate on a motion to dismiss.

Biogen also cites *Mercatus Grp. LLC v. Lake Forest Hosp.* for the principle that "even demonstrably false commercial speech is not actionable under the antitrust laws." 641 F.3d 834, 852 (7th Cir. 2011). *Mercatus* is distinguishable on multiple grounds, not the least of which was that it was a summary judgment decision rather than a motion to dismiss. Moreover, in *Mercatus*, the at-issue speech was a business's disparaging remarks about a rival, which the Seventh Circuit thought likely to be disregarded by consumers as "non-objective and highly biased." *Id*. Here, by contrast, Biogen's disparaging remarks were about its own product, a subject about which it presumably would not lie and which it would be in a position to know the most about. *Mercatus* reasoned that in the marketplace of ideas, false speech about a rival will be quickly corrected by that rival. *Id*. The same is not true when a pharmaceutical company provides false data about its own products.

In summary, considering the complaint's allegations about the combined and synergistic effects of Biogen's safety claims, payments to PBMs, and coupon program on the decision-making of patients and their doctors, the Court finds Plaintiffs have plausibly alleged that the switchover of patients from Tecfidera to Vumerity was the result of Biogen's price- and quality-obscuring efforts, rather than unobstructed competition on the merits. That is enough for Plaintiffs' antitrust claims premised on a Vumerity market switch to survive dismissal.

III. Robinson-Patman Act Claim

Count V of Plaintiffs' complaint is brought under Section 2(c) of the Robinson-Patman Act, which in its entirety reads:

> It shall be unlawful for any person engaged in commerce, in the course of such commerce, to pay or grant, or to receive or accept, anything of value as a commission, brokerage, or other compensation, or any allowance or discount in lieu thereof, except for services rendered in connection with the sale or purchase of goods, wares, or merchandise, either to the other party to such transaction or to an agent, representative, or other intermediary therein where such intermediary is acting in fact for or in behalf, or is

> subject to the direct or indirect control, of any party to such transaction other than the person by whom such compensation is so granted or paid.

15 U.S.C. § 13(c).

In *Grace v. E. J. Kozin Co.*, the Seventh Circuit interpreted Section 2(c) to reach claims of commercial bribery. 538 F.2d 170, 173 (7th Cir. 1976). In *Grace*, the executive of a seafood wholesaler convinced his company to start purchasing large volumes of seafood from a competing seafood supplier. *Id*. at 172. As it so happened, that executive was also receiving commission payments from the supplier on sales he made to the wholesaler. *Id*. Believing the supplier's payments to the executive violated Section 2(c) of the Robinson-Patman Act, the wholesaler sued the supplier. *Id*. On appeal from judgment in favor of the wholesaler, the Seventh Circuit agreed with the district court that the arrangement between the executive and supplier constituted commercial bribery actionable under Section 2(c) of the Robinson-Patman Act. *Id*. at 173.

Biogen argues that Plaintiffs' commercial bribery claim must be dismissed because Plaintiffs fail to allege that PBMs owed them any fiduciary duty. To state a commercial bribery claim, Plaintiffs must plausibly allege that a fiduciary relationship existed between them and their PBMs. *See Grace*, 538 F.2d at 173 (purpose of Section 2(c) is "to protect the integrity of the principal-agent relationship where a violation has an anti-competitive effect."); *see also 2660 Woodley Road Joint Venture v. ITT Sheraton Corp.*, 369 F.3d 732, 737 n. 4 (3d Cir. 2004) ("As a general principle, a critical element of commercial bribery is the breach of the duty of fidelity"); *Harris v. Duty Free Shoppers Ltd. P'ship*, 940 F.2d 1272, 1274 n.3 (9th Cir. 1991) ("Section 2(c) ... can be read to prohibit commercial bribery where a fiduciary relationship exists.").

Under Illinois law, "[a] fiduciary duty arises either as a matter of law or by special circumstances." *Autotech Tech. Ltd. P'ship v. Automationdirect.com*, 471 F.3d 745, 748 (7th Cir. 2006). Special circumstances can arise when "one party places trust in another so that the latter gains superiority and influence over the former." *Ransom v. A.B. Dick Co.*, 682 N.E.2d 314, 321 (1997). In determining whether special circumstances create a fiduciary duty, the Court recognizes that the "essence of a fiduciary relationship is that one party is dominated by the other." *Pommier v. Peoples Bank Marycrest*, 967 F.2d 1115, 1119 (7th Cir. 1992); *see also Amendola v. Bayer*, 907 F.2d 760, 763 (7th Cir. 1990) (fiduciary relation arises if "one person has reposed trust and confidence in another who thereby gains influence and superiority over the other."). And so while possession of "knowledge and expertise" will not transform "every expert … automatically [into] a fiduciary," a common law duty may arise when that expert "solicits another to trust him in matters in which he represents himself to be expert as well as trustworthy and the other is not expert and accepts the offer and reposes complete trust in him." *Burdett v. Miller*, 957 F.2d 1375, 1381 (7th Cir. 1992).

Previously, the Court found that Plaintiffs had not plausibly alleged a fiduciary relationship between Plaintiffs and the PBMs. In particular, the Court noted that unlike in the other cases considering similar claims, Plaintiffs had not alleged any specific marketing statements by PBMs suggesting they had held themselves out to Plaintiffs as trustworthy experts with respect to formulary design. *See In re EpiPen Direct Purchaser Litig.*, 2021 WL 147166, at *18 (D. Minn. Jan. 15, 2021) (describing allegations of PBMs' ability to "achieve lower costs" for their client plans and concomitant statements promising to "act in the best interest of [said] clients"); *In re Express Scripts, Inc., PBM Litig.*, 522 F.Supp.2d 1132, 1144–45 (E.D. Mo. 2007) (same). Plaintiffs' amended complaint alleges numerous public-facing marketing statements

whereby the PBMs hired by Plaintiffs pledged to protect the best interests of their health plan clients and use their expertise and control over formularies to promote the purchase of low cost and generic drugs. *See* Doc. 99 ¶¶ 158–162. Combined with Plaintiffs' allegations about their lack of relative expertise or visibility into how PBMs design formularies, *see id*. ¶¶ 155–56, 164–73, Plaintiffs have pleaded enough to make it plausible that PBMs owed them a fiduciary duty when designing plan formularies.

Biogen's contrary arguments are not convincing. It cites *Last Atlantis Cap. LLC v. AGS Specialist Partners* to argue that entities which "serve two masters" cannot be fiduciaries of either. 819 F.Supp.2d 708, 718 (N.D. Ill. 2010). That principle applies, Biogen argues, because PBMs market themselves as serving both plans and their members: hence, two masters with "divergent interests." Doc. 112 at 35. This is a stretch. Insureds don't hire PBMs for anything, and it seems reasonable to infer that—as far as formulary design goes—plans and their insureds would both prefer that PBMs direct insureds towards lower-cost pharmaceuticals. Biogen also argues that the contracts between Plaintiffs and PBMs disclaim all fiduciary duties, but "[a]s a general rule, on a Rule 12(b)(6) motion, the court may consider only the plaintiff's complaint." *Rosenblum v. Travelbysus.com Ltd.*, 299 F.3d 657, 661 (7th Cir. 2002). Biogen offers no reason to depart from that principle here, though it is welcome to raise this issue at the appropriate stage of proceedings.

Beyond fiduciary duty, Biogen also argues that Plaintiffs' Section 2(c) claim fails because neither PBMs nor Plaintiffs take title to Biogen's drugs. Biogen seems to draw this requirement from cases decided outside this Circuit, where courts have required Section 2(c) claims to contain some allegation that a payment passed from seller to buyer's intermediary—*i.e.*, across the buyer-seller line—or vice versa. *See Seaboard Supply Co. v. Congoleum Corp.*,

770 F.2d 367, 372 (3d Cir. 1985). The Court is unpersuaded that the PBMs or Plaintiffs must have taken title to the drugs for there to be a Section 2(c) claim. No such rule appears in *Grace*, where there was no indication that the bribed executive at any point took possession of the seafood. And the Court is satisfied with the cases cited by Plaintiffs holding that for antitrust purposes, health plans are considered purchasers of prescription drugs. Doc. 129 at 33, citing *Brillhart v. Mut. Med. Ins., Inc.*, 768 F.2d 196, 199 (7th Cir. 1985). Even accepting *arguendo* that acquisition of title matters in other contexts, formalistic adherence to that rule would ignore the practical realities of how and why prescription drugs are purchased in the United States, which would not be in the spirit of attuning the antitrust analysis "to the particular structure and circumstances of the industry at issue." *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 411 (2004); *see also A.A. Poultry Farms, Inc. v. Rose Acre Farms, Inc.*, 881 F.2d 1396, 1404–5 (7th Cir. 1989) ("[W]herever possible, standards under the Robinson-Patman Act should be conformed to standards under other antitrust laws.").

In summary, the Court finds Plaintiffs' current allegations suffice to state a plausible commercial bribery claim under Section 2(c) of the Robinson-Patman Act.

IV. RICO Claim

The Court turns last to Plaintiffs' RICO claim, which is predicated primarily on the allegations that Biogen paid PBMs to manipulate plan formularies to the detriment of generic dimethyl fumarate. Plaintiffs allege that through sustained fees and rebate payments to PBMs, Biogen formed separate RICO enterprises with each co-conspiring PBM. The purpose of each of these enterprises was to allow Biogen and its PBM partner to derive profits from the generic-defeating effects of the PBMs' manipulations, which neither Biogen nor the PBMs could have attained acting alone.

The elements of a civil RICO claim are "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *Vicom, Inc. v. Harbridge Merch. Servs., Inc.*, 20 F.3d 771, 778 (7th Cir. 1994) (internal citation omitted). A RICO enterprise is a "group of persons associated together for a common purpose of engaging in a course of conduct." *Boyle v. United States*, 556 U.S. 938, 946 (2009). If an enterprise is plausibly alleged, there must also be allegations that a defendant participated in the "operation or management of the enterprise," meaning some allegations that defendants "participated in the conduct of the 'enterprise's affairs,' not just their *own* affairs." *Richmond v. Nationwide Cassel L.P.*, 52 F.3d 640, 646 (7th Cir. 1995), quoting *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993).

Biogen contends Plaintiffs have failed to plausibly allege both the enterprise and "operation or management" elements of a RICO claim. According to Biogen, the negotiation and payment of rebates and fees in exchange for favorable drug tiering constitutes ordinary commercial activity, and two businesses acting in their individual self-interests do not constitute a RICO enterprise. *Bible v. United Student Aid Funds, Inc.*, 799 F.3d 633, 655–56 (7th Cir. 2015). On that same logic, Biogen argues that alleged acts within "the bounds of the parties' normal commercial relationships" prove only that the supposed members of a RICO enterprise were conducting their own affairs, not those of an enterprise. *United Food & Commercial Workers Union v. Walgreen Co.*, 719 F.3d 849, 855–56 (7th Cir. 2013).

The Court takes a different view of the complaint. According to Plaintiffs, the standard practice of PBMs was to serve the best interests of their client plans by placing generic versions of brand drugs in more favorable formulary tiers. Here, however, Biogen's payments caused PBMs to depart from this ordinary practice and instead make decisions that would only harm their client plans. While Biogen contends that the pursuit of profit is natural for commercial

entities, the Court finds it significant that absent Biogen's payments, the PBMs would lack any freestanding profit motive to place generic dimethyl fumarate in the same tier as Tecfidera or Vumerity. This suggests to the Court that the arrangement was an aberration from ordinary industry practice, sustainable only through Biogen's systematic payments. Thus, the Court rejects Biogen's argument that the enterprise and conduct elements of RICO have not been plausibly alleged. As this is the only substantive argument Biogen raises to challenge the adequacy of Plaintiffs' RICO claim, it survives.

CONCLUSION

For the foregoing reasons, Biogen's motion to dismiss is denied in its entirety.

Dated: January 28, 2026

April M Perry

APRIL M. PERRY
United States District Judge